

Claim Rejections: 35 U.S.C. §112

The Examiner has stated that claims 1-17, 21-24, 28-30 and 33 are rejected as being indefinite because the scope of the phrases “sufficient quantity of an ethanol composition to facilitate transport, storage, delivery and consumption” and “recreationally relevant” is unclear. Applicants respectfully submit that the Examiner has misinterpreted claim 1 and placed emphasis on the wrong portion of the phrase. Obviously, the quantity of ethanol would have little to do with facilitating transport, storage, delivery and consumption of the product. It is the capsule that should be emphasized in claim 1. The phrase “sufficient quantity of ethanol” simply describes the substance contained within a *capsule* which is designed to facilitate: *transport* (its shape allows the encapsulated beverage to be carried easily by a user in, for example, a pocket, purse or the like), *storage* (will not melt at ambient temperatures, may be stored for weeks); *delivery* (can be punctured, chewed, digested in stomach, or dissolved at a desired pH); and *consumption* (pill shape embodiment allows for easy swallowing and gastric digestion, whereas a chewable embodiment allows for easy mechanical break down of capsule and release of alcohol).

It is urged that the phrase “recreationally relevant” is easily discernable through examination of the specification. The Examiner is directed to the following passages: “...any amount of an ethanol containing composition which, alone or in combination with repeated doses of the same amount of ethanol, produces a noticeable recreational physiological effect on the consumer of such a quantity of ethanol.”(Pg. 4, Lns. 5-7); “...(approximately 1-2 ounces)...consumed in this form, alcohol can be ingested for recreational purposes...” (Pg.2, Lns. 22-24); “...first embodiment... capsule...containing... approximately 0.5 to 1.5 ounces of ethanol.” (Pg. 4, Lns.12- 17); “...consumption of between about one to ten capsules ...come within the scope of this definition of recreationally relevant quantities of ethanol capsules.” (Pg. 4, Lns. 7-8); and “... the total internal volume of the capsule is preferably between about 5 milliliters and about 50 milliliters...”. (Pg. 4, Lns. 29-30) Thus, by reading these passages it

becomes clear that the scope of “recreationally relevant” covers an alcohol volume in the capsule, whereby a physiological effect is experienced by the consumer after consumption of 1 to 10 capsules. Therefore, it is respectfully requested that this ground for rejection be withdrawn.

Claims 2-4 are rejected because the phrase “easily transportable” is considered indefinite. The Examiner is directed to the following passage. “However, in Jell-O-Shots, the alcohol is dispersed with a gelatin... and there is no encapsulating shell. As a result, such alcohol compositions are not easily transportable, have no mechanical strength, and are subject to melting or liquefaction if retained at ambient or slightly above ambient temperatures.” (Pg. 2, Lns. 35-30); “...encapsulating material to be of sufficient rigidity to sustain packaging and storage for from several minutes to several weeks...”. (Pg. 5-6 Lns.31, 1) Thus, the phrase “easily transportable” is meant to convey properties of strength and stability not found in prior art having a liquid composition similar to the present invention. This provides the advantage of being able to transport the product in, for example, a pocket, purse, box etc., because the capsule adds mechanical strength and resists phase change over a wider range of temperatures. The closest prior art is not easily transportable because it quickly melts, thereby releasing the alcohol content at an undesirable time or location. Therefore, it is respectfully requested that this ground for rejection be withdrawn.

The Examiner has stated that claim 4 is rejected as being indefinite because the scope of the phrase “easily rupturable” is unknown. It is urged that the specification clearly define what is meant by this phrase. The capsule may be easily ruptured through “breakage in consumer’s mouth...” (Pg. 5, Ln. 7); “...upon exposure of the capsule to a specific elevated or decreased pH, the encapsulating material rapidly dissolves...” (Pg. 6, Lns.13-14) Thus, it is clear that the capsule may be easily ruptured by the mechanical action of chewing, through puncture, or when exposed to low or high pH material. Therefore, it is respectfully requested that this ground for rejection be withdrawn.

The Examiner has rejected claim 5 as being indefinite because the phrase “similarly shaped” is stated to be unclear. This phrase is directed to any embodiment that has a capsule shape, such as an elliptical or elongated geometry. One knowledgeable in the art would easily be able to differentiate a capsule form of the invention from, for example, an embodiment having the shape of a “life-saver.” It is urged that the shape of a capsule is so well recognized in the art that there would be little confusion with determining whether another object is shaped like a capsule.

Claim 6 has been rejected as being indefinite because the term “approximately” is unclear to the Examiner. It is urged that the term “approximately” is a commonly used synonym for the term “about”. The term “about” used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was previously held by the Court to be clear, but flexible. (*Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968)). An analogous situation exists here because in reference to this claim, the specification states “...approximately 0.5 to 1.5 ounces...” (Pg. 4, Ln16). Therefore, Applicants respectfully request that this ground for rejection be withdrawn.

The Examiner has rejected claims 8-12 because the scope of the term “about” is said to be unclear. As previously stated, the term “about” has been held to be clear, but flexible. (*Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968)). An analogous set of facts to those found in *Eastwood* exists here and should therefore be accorded the same interpretation. Therefore, rejection of these claims is respectfully requested to be withdrawn.

Claim 15 has been rejected because the scope of the phrases “optionally” and “easy swallowing” is said to be unknown. It is urged that the specification clearly defines what is meant by these terms. The term “optionally” is directed to the waxy, synthetic or similar encapsulant that a user may choose not to digest. The Examiner is directed to the following passage. “...for such compositions, chewing and ejecting the capsule may be preferred.”(Pg. 6, Lns. 7-8); “The ethanol ball is chewed by a consumer, and the waxy encapsulant is discarded, chewed like gum, or swallowed...”(Pg. 7, Lns. 5-6) The

phrase “easy swallowing” describes any embodiment, but is particularly applicable for those having a sugar coating. The Examiner is directed to the following passage “...capsule coated with sugar... such that ...as the sugar dissolves, it ensures ease of swallowing.” (Pg. 5, Lns. 8-11) Thus, through reading the specification, the meaning of these phrases become unmistakable. Therefore, this ground for rejection is respectfully requested to be withdrawn.

Claim 17 stands rejected because the phrase “sufficiently small to permit easy passage” is unclear to the Examiner. It is urged that this phrase is definite in view of the general guidelines contained in the specification. One of ordinary skill in the art would know what is meant by “sufficiently small” in light of the general size range of the human esophagus through which the capsule material will pass. Therefore, the Examiner is respectfully requested to withdraw this ground for rejection.

Claim 21 is rejected because the scope of the phrase “various concentrations” is unclear. The specification clearly points out that the range of concentrations may vary from between “...about 5% to about 95% ethanol...” (Pg.4, Ln. 27) As previously noted above, the courts have considered the term “about” to be definite where ranges are presented. Thus, it is clear that through reading the specification, one can clearly discern the meaning of the phrase “various concentrations”. Therefore, Applicants respectfully request that this ground for rejection be withdrawn.

Claim 28 is rejected because the scope of the phrase “appearance of a garnish” is considered unclear. One familiar with cocktails will recognize that it is common practice to garnish a drink with olives. Other garnishes, such as onions, cherries, limes, lemons, and other fruits are also commonly used. Thus, it would be clear to one knowledgeable in the field through reading the specification that the “appearance of a garnish” is meant to cover all such garnishes commonly added to “dress-up” an alcoholic beverage. Therefore, this ground for rejection is respectfully requested to be withdrawn.

Claim 29 is rejected because the scope of the phrase “appearance of an olive” is unclear to the Examiner. It is urged that olives have very distinctive designs and colors that would be readily identifiable to the average consumer. Additionally, because a capsule having such a shape would most likely be viewed in association with an alcoholic beverage, an inference will likely be drawn by one knowledgeable in the field of beverages that such an object is in fact an olive. Therefore, it is respectfully requested that this ground for rejection be withdrawn.

Claim 30 does not identify a specific phrase that is being rejected. Therefore, it is respectfully requested that this ground for rejection be withdrawn.

Amendments to claims 7, 13 and 33 have been made to further clarify and particularly point out what the Applicants consider to be the invention, and should not be construed to narrow the scope of the appended claims. The Applicants submit that the amendments place each claim in condition for allowance.

Claim Rejections 35 U.S.C. § 102

Claims 1-5, 7-10, 13-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brox. However, Brox claims that ethanol is employed as a solvent for pharmaceutically active substances, dietary substance, or food supplements which, although not excluded, are not claimed in this invention. Flavorings are added to provide taste, but this can not be interpreted as being analogous to adding a food supplement because the user derives little or no nutritional value from the additive. Also, the Brox patent claims that when greater than 10% ethanol is placed in the capsule, the solvent mixture must contain at least 20%, but may contain up to about 95% by weight of partial glycerides of fatty acid. In contrast, the present invention may contain up to 95% ethanol. The subject invention encapsulates these higher percentages without the need for at least 20% by weight of partial glycerides of fatty acid. Further, the composition of Brox is not designed to induce ethanol-induced intoxicating effects, particularly in those embodiments where a pharmaceutical agent is incorporated. As the Patent Office is

aware, combining pharmaceutical agents with recreationally relevant quantities of alcohol has been widely proscribed in the medical literature. Such a combination has been shown to have immediate and severe affects on a user following ingestion.

Accordingly, Brox teaches away from the present invention in which a sufficient quantity of ethanol is delivered in an encapsulated form to induce a recreational effect similar to ingesting a social alcoholic beverage. Therefore, this ground for rejection is respectfully requested to be withdrawn.

Claim Rejections 35 U.S.C. §§102-103

Claims 1-5, 7-17 and 21 are rejected under 35 U.S.C. §102(b) as being anticipated by or in the alternative under 35 U.S.C. §103(a) as being unpatentable over Sanker et al., in light of the Handbook of Perfumes and Flavors, page 280. It urged that these references can not properly anticipate a claim, because the combinations of reference do not teach every element of the claim. Sanker et al. discloses a gelatin flavor bead that *must* first be placed in a beverage to dissolve and release its content. Thus, to obtain the benefit of that product, one must first mix the material with another. Nowhere does Sanker et al. disclose or suggest that the capsule may be chewed and swallowed. In contrast, a user of the present product may place one or more capsules into his/her mouth and derive all of the benefit immediately without having to first dissolve the material in a beverage (although this is an option). The Handbook of Perfumes and Flavors adds nothing to Sanker et al. in this regard. Therefore, the combination of references can not anticipate the present invention. Withdrawal of this ground for rejection is therefore respectfully requested.

The Examiner has also stated that it would have been obvious to use ethanols as flavor carriers. The basis for this opinion is that certain well known flavor formulations, e.g. Brandy (Cognac) No.1, may contain from 89.2% to 95% ethanol. However, in Sanker et al. the quantity of flavor formulation is stated to be between 0.1mg and 400mg. It is stated that the flavorings are used primarily to flavor a coffee beverage. Applicant

submits that it is well known the total alcohol content of such flavorings for coffees and other confections have historically been of such a low total amount that inebriation effects resulting from consumption of the contained alcohol are essentially negligible. Thus, although the ethanol content of a "Brandy flavoring" may reach 95%, the total volume of alcohol present in the beverage is negligible and can not be considered to fall within the range of "recreationally relevant" quantities as defined herein. In contrast, each capsule of the present invention contains a recreationally relevant amount of alcohol sufficient to induce a physiological effect in the consumer upon consumption of 1-10 capsules. Hence, even if a user of the present invention were to consume only one capsule, he/she would be absorbing a quantity of ethanol that is several orders of magnitude higher than that contained in an average bead described in Sanker et al.

Therefore, the two inventions can not be obvious variants of each other because they are specifically designed to accomplish contrasting results. In fact, Sanker et al. does not disclose or suggest use of the flavor beads with alcoholic beverages. As the Examiner has pointed out, ethanol has been widely used as a flavor carrier because of its solubility characteristics. Hence one knowledgeable in the art would know that such composition may be used in confections and drinks as a flavoring agent, but not necessarily as an alcoholic beverage. As previously stated, the prior art teaches away from using quantities of such flavoring that would produce a noticeable recreational physiological effect on a consumer. Finally, the prior art references, when combined, do not teach or suggest all the claim limitations. Therefore, Applicants respectfully request reconsideration and withdrawal of this 35 USC § 103 rejection.

With regard to *In re Levin* the applicant urges that use of ethanol based compositions in a chewable, ingestible capsule form for the purpose of inducing a recreational physiological effect on a consumer produces a new, unexpected, and useful function as required by the Courts. The present invention allows a user to obtain the effects of ethanol intake without requiring a separate beverage. Prior art documents require dissolution of the capsule in a separate aqueous solution. Further, once the capsule has dissolved, a quantity of ethanol is released which is insufficient to induce in a

user, the effects described in the present application. Thus, the present invention provides a new, unexpected and useful function. Withdrawal of this ground for rejection is therefore respectfully requested.

Claim Rejections 35 U.S.C. §103

The Examiner has stated that it would have been obvious to modify the product of Sanker et al. so as to make it appear to be a garnish because Sanker et al. teaches the production of oblong shapes. Applicants respectfully find this ground for rejection unsupportable in light of Sanker et al.'s disclosure. In the present invention the garnish is used specifically to provide an alcohol "kicker" that may be punctured to release a sufficient quantity of alcohol to "refresh" or increase the alcohol content of a drink. The purpose is to induce a "recreational physiological effect" in the user. In no way can Sanker et al., which describes "flavor beads", be extended to suggest or motivate another to design a highly alcoholic garnish shaped capsule. Sanker et al. does not even discuss the alcoholic effects of using the "flavor bead". The only mention of alcohol in that patent is in reference to it as a solvent for specific flavorings.

Further, Sanker et al. does not mention or suggest any design variability in bead shape that would lead one to consider extending it to a garnish. The Applicant contends that it is inappropriate hindsight analysis to suggest that one would be motivated by Sanker et al.'s generically shaped flavor bead to make a capsule colored and shaped in the form of an olive, and which contains a alcohol concentration several orders of magnitude higher than that contained in the flavor bead. Reconsideration and withdrawal of this 35 USC § 103 rejection is respectfully requested.

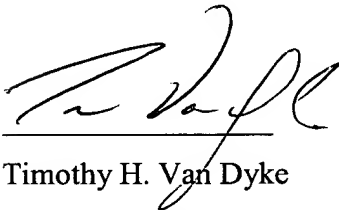
Claims 23-24 stand rejected as being unpatentable over Sanker et al. in view of McMahon et al. The Examiner has stated that it would have been obvious to use the capsule wall of McMahon et al. in the product of Sanker et al. It is urged that even if the McMahon et al. capsule were used in the present invention, the final product would still not be obvious in light of Sanker et al. for the reasons disclosed previously in this

response. Therefore, Applicants respectfully request that this ground for rejection be withdrawn.

Applicants submit that all grounds for rejection of claims presented herein have been addressed and overcome. Amendments made to the claims should in no way be construed as limiting the scope of the original claims and are made for the sole purpose of clarifying the meaning of terminology presented therein. All original elements and their equivalents are hereby retained. Accordingly, claims 1-17, 21-24, 28-30 and 33 will be before the Examiner for prosecution on the merits.

Applicant invites the Examiner to call the undersigned if clarification is needed on any aspect of this response, or if the examiner believes that any valid basis remains for maintaining the rejection of the claims presented in this application after entrance and consideration of the remarks presented herein.

Respectfully submitted,



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Addendum

Claim 7 (Amended)

7. The capsule according to claim 6 wherein said ethanol contained within the cavity of said capsule is pure, substantially pure, or diluted ethanol, for addition to and dissolution in an aqueous solution [such as a fruit juice, soft drink or in water], or wherein the alcohol is mixed with water, syrup, gel, or flavoring [and the like], such that the capsule may be directly dissolved in a person's mouth, chewed or swallowed for dissolution inside the digestive tract.

Claim 13 (Amended)

13. The capsule according to claim 1 wherein said capsule comprises a non-toxic, flexible material as the encapsulant to contain deliver the ethanol composition for recreational purposes.

Claim 33 (Amended)

33. The capsule according to claim 1 wherein the alcoholic composition [beverage] is a wine, spirit, mixed drink, brandy, flavored alcohol, tequila, vermouth, gin, vodka, or a mixture thereof.